PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Racz et al.

Serial No.: 10/694,235

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For: SAFETY SPINAL NEEDLE
(As Amended)

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BRIEF ON APPEAL

Mail Stop Appeal Brief – Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief on Appeal is submitted as a single copy pursuant to 37 C.F.R. § 41.37, and in the format required by 37 C.F.R. § 41.37(c)(1). Authorization is provided to charge the deposit account in the amount of $310.00 for the fee under 37 C.F.R. § 41.20(b)(2) for filing a brief in support of an appeal. Please apply any charges or any credits in connection with the filing of this Appeal Brief to Deposit Account No. 20-1469.

I. REAL PARTY IN INTEREST

The real party in interest in the present pending appeal is Custom Medical Applications, as recorded with the United States Patent and Trademark Office on January 11, 2010, at Reel 023770, Frame 0032.

II. RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's representative, nor the Assignee is aware of any prior or pending appeal or interference which would directly affect, be directly affected by, or have any bearing on the Board's decision in the present pending appeal.

III. STATUS OF THE CLAIMS

Claims 1, 3-9, 12-23, 25-32, and 34-38 are pending in the application.

Claims 7, 13, 19, 22, and 26 have been withdrawn from consideration.

Claims 2, 10, 11, 24, and 33 were cancelled without prejudice or disclaimer.

Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 34-38 stand rejected.

No claims are allowed.

The rejection of claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 34-38 is being appealed.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the Final Office Action of August 19, 2011.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Under the provisions of 37 C.F.R. § 41.37(c)(1)(v), the following summary of claimed subject matter is made. The following summary is in accordance with the rule, at least for the reason that the rule does not require any particular format for this section of the Brief on Appeal. Appellant respectfully notes that the commentary to the rules provides that the "[a]ppellant may include any other information of record which will aid the Board in considering the subject matter of each independent claim." 69 FR 49976, Comment 53, third column, August 12, 2004.

All citations to the Specification of the instant application, in this section and in the following sections of the Brief on Appeal, are to the as-filed Specification.

A) The invention includes a flexible spinal needle catheter assembly, for example, as recited in claim 1. Specification, *e.g.*, at **[0030]**. Specifically, claim 1 is drawn to:

A flexible spinal needle catheter assembly 10 (Id.) comprising:

a flexible needle catheter 15 fabricated of plastic (Id., *e.g.*, at **[0018]**; **[0036]**; and **[0054]**) and having a sufficiently high tensile strength to maintain structural integrity during and after insertion into a patient's body and retraction therefrom (Id.), but also possesses sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom (Id., *e.g.*, at **[0018]** and **[0036]**), said flexible needle catheter 15 defining a hollow bore for conveying medicating agent therethrough (Id., *e.g.*, at **[0036]** and **FIG. 3**), said bore extending through a length of said flexible needle catheter 15 (Id., *e.g.*, at **[0036]** and **FIGs. 1**, **3**, and **5**), said flexible needle catheter 15 having a proximal end which defines a leading edge 29 (Id., *e.g.*, at **[0037]** (as amended on October 30, 2010));

a support needle 19 releaseably secured to said flexible needle catheter 15 (Id., *e.g.*, at **[0018]** and **[0040]**), said support needle 19 being removably disposed within said hollow bore of said flexible needle catheter 15 (Id., *e.g.*, at **[0011]**; **[0015]**; **[0018]**; **[0036]**; **[0040]**; and **FIGs. 1**, **2**, and **5**), said support needle 19 having a first end 33 which defines a pencil point, non-cutting piercing point 22 configured for penetrating the dura mater of a patient (Id., *e.g.*, at **[0012]**;

[0016]; and **[0033]**), said support needle 19 having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly 10 from a dura mater of a spine of a patient, subsequent to an insertion of said assembly 10 through the dura mater, a puncture opening produced by said insertion being of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly 10 within said dura mater (Id., *e.g.*, at **[0015]**; **[0016]**; and **[0033]**), said support needle 19 defining a hollow lumen which extends along a length of said support needle 19 and an opening 28, defined proximate said first end 33, which communicates the environment with said lumen (Id., *e.g.*, at **[0033]**), said support needle 19 being positionable in two conditions relative to said flexible needle catheter 15 (Id., *e.g.*, at **[0016]**; **[0032]**; **[0033]**; and **[0055]**-**[0057]**); in a first condition said support needle 19 being positioned with said first end 33 of said support needle 19 being positioned outside of said bore of said flexible needle catheter 15, said non-cutting piercing point 22 and said opening 28 being positioned outside of said bore (Id., *e.g.*, at **[0016]**; **[0055]**; and **FIG. 5**), the opening 28 being positioned contiguous to the leading edge of the flexible needle catheter 15 (Id., *e.g.*, at **[0033]**; **[0037]** (as amended on October 30, 2010); and **FIG. 5**) and in a second condition said support needle 19 being removed from within said hollow bore of said flexible needle catheter 15 (Id., *e.g.*, at **[0056]** and **[0057]**), and

a solid stylet 17, releaseably secured within said lumen (Id., *e.g.*, at **[0056]** and **[0057]**), said stylet 17 being positioned in a first condition to preclude access from the environment to said lumen through said opening (Id., *e.g.*, at **[0032]** and **[0055]**).

The arrangement of the claimed catheter assemblies, wherein a support needle with a piercing point is disposed within the bore of a flexible catheter, provides several advantages of the invention. For example, the flexible catheter remains after insertion and removal of the support needle. Because this catheter that remains is flexible, it has "sufficient transverse flexibility to deform and accommodate patient motion after insertion," and "reduce patient irritation." The claimed catheter assemblies also advantageously eliminate the need for "threading a catheter through a needle or installing an adapter." Specification, at **[0011]**. Moreover, "[p]lacement of the flexible needle (*i.e.*, flexible needle catheter) over the inserting

needle (*i.e.*, support needle) allows a larger diameter flexible needle to be inserted," and "[t]he resulting improved diameter flexible needle allows easier and faster flow of either CSF or medicating agents." Id.

B) The invention also includes a flexible spinal needle assembly for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, for example, as recited in claim 16. Specification, *e.g.*, at **[0030]**. Specifically, claim 16 is drawn to:

A flexible spinal needle assembly 10 for inserting a distal end of a flexible spinal needle 15 through dura mater into a spine of a patient (Id.), said flexible spinal needle assembly 10 comprising:

a flexible needle 15 having a leading edge 29, and made of a material that has a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body (Id., *e.g.*, at **[0018]**; **[0036]**; and **[0054]**), but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom (Id., *e.g.*, at **[0018]** and **[0036]**), said flexible needle 15 defining an internal bore through a length thereof (Id., *e.g.*, at **[0036]**; and **FIGs. 1**, **3**, and **5**);

a support needle 19 having a proximal end and a pencil point non-cutting piercing point 22 at a distal end 33 (Id., *e.g.*, at **[0016]** and **[0033]**), said support needle 19 being releaseably secured to said flexible needle 15 (Id., *e.g.*, at **[0018]** and **[0040]**) to resist relative motion between a distal end 29 of said flexible needle 15 and said pencil point non-cutting piercing point 22 during insertion of said flexible spinal needle assembly 10 into a patient (Id., *e.g.*, at **[0017]**; **[0018]**; and **[0040]**), the support needle 19 defining an interior lumen and an opening 28, said opening 28 being adapted to communicate the interior lumen with the exterior of said support needle 19 (Id., *e.g.*, at **[0033]**; and **FIGs. 1** and **5**);

wherein said flexible needle 15 is carried exterior to said support needle 19 to expose said non-cutting piercing point 22 when said assembly 10 is positioned for said inserting (Id., *e.g.*, at **[0016]** and **[0055]**; and **FIG. 5**), and

wherein said support needle 19 is positionable in two conditions relative to said flexible needle 15 (Id., *e.g.*, at **[0016]**; **[0032]**; **[0033]**; and **[0055]-[0057]**); in a first condition said

support needle 19 is positioned within said bore of said flexible needle 15 with said distal end 33 of said support needle 19 being positioned outside of said internal bore of said flexible needle 15 (Id., *e.g.*, at **[0016]**; **[0055]**; and **FIG. 5**), said non-cutting piercing point 22 and said opening 28 being positioned outside of said bore (Id., *e.g.*, at **[0033]**; **[0037]**; and **FIG. 5**); and in a second condition said support needle 19 being removed from within said bore of said flexible needle catheter 15 (Id., *e.g.*, at **[0056]** and **[0057]**).

C) The invention also includes a flexible spinal needle, for example, as recited in claim 25. Specification, *e.g.*, at **[0030]**. Specifically, claim 25 is drawn to:

A flexible spinal needle 10 (Id.) comprising:

a support needle 19 having a pencil point 22, non-cutting piercing tip 27 (Id., *e.g.*, at **[0016]** and **[0033]**), said support needle 19 defining an interior lumen and an opening, said opening communicating said interior lumen with the exterior of said support needle 19 (Id., *e.g.*, at **[0033]**; and **FIGs. 1** and **5**);

a flexible needle body 15 comprising an elongated hollow tube and made of a material that has a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body (Id., *e.g.*, at **[0018]**; **[0036]**; and **[0054]**), but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom (Id., *e.g.*, at **[0018]** and **[0036]**), said flexible needle body 15 configured to be removably and slidably mounted on an exterior of said support needle 19 (Id., *e.g.*, at **[0011]**; **[0015]**; **[0055]**; and **FIGs. 1**, **2**, and **5**), said flexible needle body 15 defining a leading edge 29, said leading edge 29 being positioned contiguous to said opening 28 of said support needle 19 (Id., *e.g.*, at **[0033]**; **[0037]**; and **FIG. 5**); and

a flexible kink sleeve 18 disposed on a portion of said flexible needle body 15 (Id., *e.g.*, at **[0049]** and **[0050]**), said flexible kink sleeve 18 being configured to prevent kinking of said flexible needle body 15, when said flexible needle body 15 is bent beyond a flexible structural resilience thereof during use (Id.),

wherein said support needle 19 is positionable in two conditions relative to said flexible needle body 15 (Id., *e.g.*, at **[0016]**; **[0032]**; **[0033]**; and **[0055]**-**[0057]**); in a first condition said

flexible needle body 15 is mounted on said exterior of said support needle 19, said support needle 19 being positioned with said first end 33 of said support needle 19 extending beyond said leading edge 29 of said flexible needle body 15 (Id., *e.g.*, at **[0016]**; **[0033]**; **[0037]**; **[0055]**; and **FIG. 5**), and in a second condition said support needle 19 is removed from physical contact with said flexible needle body 15 (Id., *e.g.*, at **[0056]** and **[0057]**).

D) The invention also includes a flexible spinal needle assembly, for example, as recited in claim 27. Specification, *e.g.*, at **[0030]**. Specifically, claim 27 is drawn to:

A flexible spinal needle assembly 10 (Id.) comprising:

a support needle 19 comprising a first end 33 defining a pencil point, non-cutting piercing point 22, and a hollow bore with an opening 28 proximate said first end 33 (Id., *e.g.*, at **[0016]**; **[0033]**; and **FIGs. 1** and **5**) allowing access to said bore (Id., *e.g.*, at **[0033]**; and **FIGs. 1** and **5**); and

a flexible needle 15 removably and slidably mounted on an exterior portion of said support needle 19 such that said first end 33 of said support needle 19 protrudes from said flexible needle 15 exposing said pencil point, non-cutting piercing point 22 and said opening 28 (Id., *e.g.*, at **[0011]**; **[0015]**; **[0016]**; **[0055]**; and **FIGs. 1, 2**, and **5**), said flexible needle 15 made of a material having a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body (Id., *e.g.*, at **[0018]**; **[0036]**; and **[0054]**), but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom (Id., *e.g.*, at **[0018]** and **[0036]**) and having a leading edge 29 positioned contiguous to the opening 28 of the support needle 19 after insertion (Id., *e.g.*, at **[0033]**; **[0037]**; and **FIG. 5**), wherein said flexible needle 15 has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle 15 (Id., *e.g.*, at **[0018]** and **[0036]**), said flexible needle 15 defining a lumen therein for transporting a medicinal agent (Id., *e.g.*, at **[0036]** and **FIG. 3**);

wherein said support needle 19 is positionable in two conditions relative to said flexible needle 15 (Id., *e.g.*, at **[0016]**; **[0032]**; **[0033]**; and **[0055]-[0057]**); in a first condition said

support needle 19 is positioned with said first end 33 of said support needle 19 extending beyond said leading edge 29 of said flexible needle 15 (Id., *e.g.*, at **[0016]**; **[0033]**; **[0037]**; **[0055]**; and **FIG. 5**), said non-cutting piercing point 22 and said opening 28 being positioned beyond said leading edge 29, the opening 28 being positioned contiguous to the leading edge 29 (Id., *e.g.*, at **[0033]**; **[0037]**; and **FIG. 5**), and in a second condition said support needle 19 being removed from physical contact with said flexible needle 15 (Id., *e.g.*, at **[0056]** and **[0057]**).

VI. GROUNDS OF REJECTION TO BE REVIEWED

A) Whether claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 35 are rendered obvious under 35 U.S.C. § 103(a) by U.S. Patent 5,871,470 (hereinafter "McWha"), in view of U.S. Patent 5,250,035 (hereinafter "Smith");

B) Whether claims 30 and 31 are rendered obvious under 35 U.S.C. § 103(a) by McWha and Smith, in further view of U.S. Patent Publication 2005/0070881 (hereinafter "Gribbons"); and

C) Whether claims 34, 36, 37, and 38 are rendered obvious under 35 U.S.C. § 103(a) by McWha and Smith, in further view of U.S. Patent Publication 2004/0236307 (hereinafter "Klein").

VII. ARGUMENT

Legal standard.

Under the Patent Act, a person "shall be entitled to a patent" unless one of the conditions for patentability set forth in the statute is not satisfied. 35 U.S.C. § 102. For example, a person otherwise entitled to a patent may not obtain the patent "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

The Examiner bears the initial burden of presenting a *prima facie* case of unpatentability under 35 U.S.C. § 103. In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if that burden is met does the applicant have the burden of coming forward with evidence or argument. Id. "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). If a *prima facie* case of unpatentability has been articulated by the Examiner, patentability is determined on the totality of the record, by a preponderance of evidence, and with due consideration to the persuasiveness of all rebuttal arguments and evidence offered by the applicant. Id.; In re Sernaker, 702 F.2d 989, 996-7 (Fed. Cir. 1983); In

re Soni, 54 F.3d 746, 749-51 (Fed. Cir. 1995) (evidence of unexpected and substantially improved results in Specification). On appeal, "the Board reviews the particular finding(s) contested by an appellant ***anew*** in light of all the evidence and argument on that issue." Ex parte Frye, Appeal No. 2009-006013, 10 (B.P.A.I. 2010) (precedential) (emphasis added).

To establish a *prima facie* case of obviousness, the subject matter of a claim "as a whole" must have been obvious in view of the cited references. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1537 (Fed. Cir. 1983). Thus, the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the claim elements. KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007); In re Wilson, 424 F.2d 1382, 1385 (C.C.P.A. 1970); *see also* Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987) (claimed invention as a whole includes every element of claim). Also, properties of a claimed invention that are disclosed in the application, even if they are inherent or not explicitly recited in a claim, must be considered part of the claimed invention "as a whole." In re Antonie, 559 F.2d 618, 620 (C.C.P.A. 1977); *see also* In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (obviousness cannot be predicated on inherent features that are not known).

Moreover, in ascertaining whether the claimed subject matter as a whole would have been obvious, the Examiner must also determine the content of the prior art "as a whole." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1550-1552 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Thus, a reference cannot be combined to render a claim obvious if the reference teaches away from the subject matter of the claim. In re Grasselli, 713 F.2d 731, 743 (Fed. Cir. 1983). A reference "teaches away" from a claim when a person of ordinary skill, upon reading the reference, "would be led in a direction divergent from the path [] taken" by the inventor. In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994). A reference also teaches away from a claim when its modification would produce an inoperable device. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001). In this context, a reference must be considered not only for what it expressly teaches, but also for what it inherently teaches, and for what it fairly suggests. In re Grasselli, 713 F.2d, at 743 (inherent teachings of prior art); In re

Baird, 16 F.3d 380, 383 (Fed. Cir. 1994) (what the prior art fairly suggests).

After arriving at an understanding of the subject matter of the claim as a whole that accounts for every element of the claim and disclosed inherent properties of its subject matter, the Examiner must articulate a reason or motivation that would have existed at the time of the invention to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418. There would have been no such motivation when the proposed modification or combination would have rendered the prior art unsatisfactory for its intended purpose. In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984).

A) Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 35 were not obvious to one of ordinary skill in the art at the time the invention was made, notwithstanding McWha and Smith.

(1) Separate argument supporting claim 1

(i) Claim construction

In construing claim limitations, "the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Plastic flexible needle catheter: Claim 1 recites that the claimed flexible needle catheter assembly comprises, *inter alia*, "a flexible needle catheter fabricated of plastic... possess[ing] sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom."

Thus, claim 1 is drawn not just to needle catheter assemblies, but specifically to those that comprise a ***plastic*** needle catheter that is ***flexible***. The Specification specifically enumerates several examples of suitable plastic materials for constructing the claimed needle catheters. Specification, at **[0018]** (medical grade plastic materials, *e.g.*, polyester shrink tube or

similar materials); **[0036]** (conventional plastic catheter material); and **[0054]** (polyester shrink tubing and other polymers). As explained in the Specification,

> Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from the patient. A flexible needle desirably possesses ***sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation*** from the presence of a foreign body.
>
> Id., at **[0036]** (emphasis added).

Claim 1 (as well as every other claim pending in the application) expressly recites that the flexible needle has "sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation." Accordingly, claim 1 expressly recites these properties of the claimed flexible plastic needle catheters, as set forth, *supra*.

Support needle: Claim 1 further recites that the "flexible needle catheter defin[es] a hollow bore," and that the flexible needle catheter assembly also comprises "a support needle releaseably secured to said flexible needle catheter, said support needle being removably disposed within said hollow bore of said flexible needle catheter."

FIG. 1 of the as-filed application depicts the support needle, and **FIG. 3** depicts the hollow bore defined by the flexible needle catheter. Moreover, the Specification describes for one of skill in the art the specific meaning of the elements, "releaseably secured" and "removably disposed," which define the relationship between the claimed support needle and the flexible needle catheter with its hollow bore. For example, the Specification describes the "[p]lacement of the flexible needle (*i.e.*, the flexible needle catheter) over the inserting needle (*i.e.*, the support needle)," and explains that this arrangement "allows a larger diameter flexible needle to be inserted," as compared to prior spinal catheters. Id., at **[0011]**. The Specification further explains, "It is desirable to prevent inadvertent premature removal of the support needle 19 from the flexible needle 15" (Id., at **[0040]**), and both explains (Id., at **[0040]**) and depicts (Id., at **FIGs. 1**, **2**, and **5**) examples of how the support needle is "releaseably secured" to accomplish this prevention.

Claim 1 further recites that the support needle "defin[es] a hollow lumen which extends along a length of said support needle and an opening, defined proximate said first end."

Prior to removal of the support needle from within the hollow bore of the flexible needle catheter (in the first condition), "the opening [is] positioned ***contiguous*** to the ***leading edge*** of the flexible needle catheter" (emphasis added).

Appellant respectfully submits that the meaning of the elements of claim 1 that describe the relationship of the claimed support needle opening and the flexible needle catheter (*i.e.*, the opening [is] positioned contiguous to the leading edge of the flexible needle catheter) would be clear and unambiguous to one of skill in the art. One of ordinary skill in the art would give the terms, "contiguous" and "leading edge," their normal meaning, such that the leading edge of the flexible needle catheter would be understood to be the edge defined by an intersection of surfaces of the flexible needle catheter that leads all other edges defined by intersections of surfaces of the flexible needle catheter as the spinal needle and catheter assembly is inserted into a patient; *i.e.*, the leading edge is the edge that is "first" as the assembly is inserted. An opening would be understood to be contiguous with such a leading edge if these elements were connected on a surface without a break or interruption.

If there were any doubt as to the meaning of this relationship, the Specification and Drawings clarify that the foregoing interpretation is correct. For example, the Specification describes that "[t]he tip 29 of flexible needle 15 may be tapered into a curve to blend smoothly into the edge of support needle 19." Id., at **[0037]**. **FIG. 5** provides a view of the tip of the flexible needle and support needle in the "first condition" described in claim 1; *i.e.*, with the support needle positioned with its tip positioned outside of the bore of the flexible needle catheter. As is clear from **FIG. 5** of the as-filed application, the tip (first end) 27 of the support needle with its opening 28 is defined by a single edge/surface that becomes the "leading edge" of the flexible needle 15 at its tip 29.

(ii) Analysis

Claim 1 is not rendered obvious by McWha and Smith, because these references, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading

edge of the plastic, flexible needle catheter. McWha and Smith do not render claim 1 obvious for the additional reason that there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha (referred to therein as a "cannula") out of a flexible plastic material.

1. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle catheter "fabricated of plastic," and having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle catheter "defin[es] a hollow bore for conveying medicating agent therethrough... [and a] support needle being removably disposed within said hollow bore of said flexible needle catheter," as is recited by the claim. Thus, the cited combination of references does not yield the claimed subject matter.

McWha does not describe a plastic flexible needle catheter, and this is a fact that has been recognized by the Examiner. Final Office Action of August 19, 2011, at p. 6. In contrast to the claimed plastic flexible needle catheters, both of the needle cannulas of McWha (including the epidural needle cannula asserted by the Examiner to correspond to the claimed plastic, flexible needle catheters) are preferably formed from stainless steel. McWha, at col. 7, line 67, to col. 8, line 2. In fact, stainless steel is the ***only*** specific material identified in McWha as one from which the cannulas described therein may be fabricated.

Importantly, the non-plastic nature of the material used to fabricate McWha's cannulas is emphasized by the context in which it appears. In the paragraph of McWha describing their preferable stainless steel composition, other elements of McWha's needle set are explicitly recited to be able to be constructed from plastic. For example, McWha states that "[n]eedle hubs may be formed from thermoplastic materials" (Id., at col. 7, lines 63-64), and "[o]ther components (besides the cannula and spinal needle) of the several embodiments of the assembly of the invention such as spacer and threaded washer may also be formed from thermoplastics" (Id., at col. 8, lines 2-4). Thus, the cannula and spinal needle are expressly omitted from the set of assembly components in McWha that may be fabricated from plastic.

As would be appreciated by one of skill in the art, stainless steel is not a flexible material, and would not be thought capable of being fabricated into a flexible cannula/catheter

with "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," as claimed. The arrangement of the claimed catheter assemblies, wherein a support needle with a piercing point is disposed within the bore of a flexible catheter, provides several advantages of the invention. For example, not only does the flexible catheter that remains after removal of the support needle have "sufficient transverse flexibility to deform and accommodate patient motion after insertion," and "reduce patient irritation," as recited in the claim, but the claimed catheter assemblies eliminate the need for "threading a catheter through a needle or installing an adapter." Specification, at **[0011]**. Moreover, "[p]lacement of the flexible needle (*i.e.*, flexible needle catheter) over the inserting needle (*i.e.*, support needle) allows a larger diameter flexible needle to be inserted," and "[t]he resulting improved diameter flexible needle allows easier and faster flow of either CSF or medicating agents." Id.

The express and inherent teachings of Smith are not such that they may be combined with the inflexible, steel cannula of McWha, using only the knowledge and skill of one of ordinary skill in the art at the time of the invention, to yield a plastic flexible needle catheter having the attributes of those claimed.

While Smith describes a cannula that comprises a plastic "elongated member" with "a greater self-lubricating property" than steel (Smith, at col. 3, lines 12-22), the cannula of Smith's system is in all other ways unlike, and incompatible with, the presently claimed flexible needle catheters. For example, the cannula of Smith is inserted into a previously formed puncture in a patient's back (Id., at col. 3, lines 22-25), and then used to position a spinal catheter in the patient, after which the cannula is subsequently removed (Id., at col. 5, lines 15-20).

Appellant respectfully notes that it is the ***spinal catheter*** of Smith's system, and not its plastic cannula, that is anchored to the patient (Id., at col. 5, lines 19-20) and through which medication is delivered (Id., at col. 3, lines 29-33). In contrast, the presently claimed flexible needle catheter "convey[s] medicating agent" to a patient through its hollow bore, while providing all the benefits of its flexibility and dimensions, which are not properties delivered to the removable positioning cannula of Smith by its plastic composition.

Accordingly, McWha and Smith do not render obvious a flexible needle catheter assembly comprising a plastic, flexible catheter, as claimed, with all of its properties and advantages. McWha describes a steel (or non-plastic) catheter, while Smith is silent as to the composition of its catheter. Smith describes a plastic removable positioning cannula, but this element in Smith is not used "for conveying medicating agent therethrough," as claimed, and it does not remain in the patient's body after positioning of a catheter. Moreover, the reasons stated in Smith for the plastic construction of the positioning cannula (*i.e.*, self-lubrication) are not the reasons the claimed flexible needle catheters are fabricated from plastic. Thus at most, Smith teaches only that other components of a catheter assembly may be made of plastic; a fact already acknowledged by McWha, wherein all of the elements of its needle set ***except*** the catheter (referred to as a cannula in McWha) are made from plastic.

For the foregoing reasons, a person of ordinary skill in the art at the time the present invention was made would not have combined the elements of McWha and Smith according to their purposes disclosed therein, or according to their normal and expected functions, to produce the flexible needle catheters that are an express element of claim 1 and its dependent claims.

2. A person of ordinary skill in the art at the time of invention would not have been motivated to modify the preferably steel needle cannula of McWha (McWha, at col. 7, line 67, to col. 8, line 2) to be fabricated of plastic having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," as recited in claim 1. Fabricating the spinal or epidural needle cannula of McWha from flexible plastic would render this reference unsuitable for its intended purpose and produce an inoperable needle set.

McWha describes that a bevel of the preferably steel needle defines what appears to be a cutting point at a leading edge on a side of the epidural needle comprising the needle cannula. Id., at col. 4, lines 57-65; and FIGs. 4 and 4a. Additionally, McWha teaches that the epidural needle comprising the needle cannula is advanced into the epidural space ***through the skin*** of a patient. Id., at col. 5, lines 7-16. One of ordinary skill in the art would understand that fabricating the epidural needle and cannula of McWha from plastic having sufficient transverse

flexibility to deform and accommodate patient motion after insertion would appear to render the epidural needle and cannula unsatisfactory for its intended purpose; *i.e.*, a flexible plastic needle and cannula with a correspondingly flexible bevel at its tip would destroy the ability of the device to neatly cut and penetrate the skin and advance into the epidural space. *See* Id., at col. 5, lines 7-16. Thus, if the needle set of McWha were modified as proposed by the Examiner to have a plastic cannula element, the needle set would no longer function to establish access of delivered medicaments to the epidural space.

Smith reinforces the understanding that the proposed modification of McWha to comprise a flexible plastic needle cannula would have been undesirable, as the plastic cannula taught by Smith must be introduced into a previously-formed epidural passage made by a known-type introducer (not shown). *See* Smith, col. 3, lines 19-25. Thus, a person of ordinary skill would not be led to believe from Smith that the needle cannula of McWha could be fabricated of plastic and continue to function to penetrate the skin and tissue of a patient.

For the foregoing reasons, a person of ordinary skill in the art at the time the present invention was made would not have had a reason or motivation to combine the elements of McWha and Smith according to their purposes disclosed therein to produce the flexible needle catheters of claim 1 and its dependent claims.

3. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle catheter having removably disposed therein a support needle "defining a hollow lumen which extends along a length of said support needle and an opening, defined proximate said first end," where "the opening [is] positioned contiguous to the leading edge of the flexible needle catheter," as is recited by the claim. Thus, the cited combination of references does not yield the claimed subject matter.

McWha does not describe a spinal needle (asserted by the Examiner to correspond to the claimed support needle) that has an opening positioned contiguous to the leading edge of the flexible needle catheter. Rather, referring to FIG. 3 of McWha, McWha describes that, as the spinal needle is advanced so that the pointed distal end 26 projects distance "x" beyond the open distal end 16 of the epidural needle 12, the spinal needle openings 29 will be spaced from a leading edge of the bevel at the open distal end 16 of the epidural needle 12.

McWha, at FIG. 3 (compare with FIG. 2); and col. 5, lines 16-18. Referring to FIGs. 4 and 4a, the bevel 34 or 38 of the epidural needle 12 defines a cutting point (Id., at col. 5, lines 25-29) at a leading edge on a side of the epidural needle 12. Id., at FIGs. 4 and 4a; and col. 4, lines 57-65.

Accordingly, as the spinal needle of McWha is advanced beyond the open distal end of the epidural needle, its openings will be contiguous with an edge defined by an intersection between the surface of the bevel and the ***inner*** surface of the epidural needle defining the hollow bore. Id., at col. 4, lines 57-65; col. 5, lines 16-18 and 25-29; and FIGS. 2-4a. However, this edge, which is contiguous with the spinal needle openings in McWha, is not the "leading edge" of the epidural needle, because the edge defined by the intersection between the surface of the bevel and the ***outer*** surface of the epidural needle "leads" as the spinal epidural needle set is advanced into the patient. Id.

Smith does not supply this element of claim 1 that is missing from McWha. Smith describes a stylet having a pointed end that appears to block access to the bore of the cannula, because spinal fluid is aspirated through the cannula only after removal of the stylet from the cannula. Smith, at col. 5, lines 8-11.

For the foregoing reasons, a person of ordinary skill in the art at the time the present invention was made would not have combined the elements of McWha and Smith according to their purposes disclosed therein, or according to their normal and expected functions, to produce the support needles that are an express element of claim 1 in the configuration recited therein.

(iii) Examiner's position

The Examiner asserts that Smith describes a flexible plastic needle catheter, such that the combination of McWha and Smith would produce "the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof." Final Office Action of August 19, 2011, at p. 6. Appellant respectfully disagrees with this assertion, and that this assertion would render claim 1 obvious even if it were correct.

First, the Examiner is incorrect that McWha describes a "flexible" needle catheter. As set forth, *supra*, it is preferred in McWha that the epidural needle[1] is fabricated of stainless steel, and this is the only material specifically identified as one from which the epidural needle may be fabricated. McWha, at col. 7, line 67, to col. 8, line 2. Moreover, this preferred example in McWha is not accidental; the epidural needle of McWha must be able to adequately cut and penetrate the skin and underlying tissue of a patient. Stainless steel is inflexible, which is a primary reason that it is a preferred material for fabricating cutting and piercing instruments. Notably, ***all of the other elements*** in the needle set (*e.g.*, the needle hub, spacer, and washer) are recited to be able to be made from plastic. Id., at col. 6, line 63, to col. 8, line 5. If the cutting and penetrating epidural needle of McWha were able to be made of plastic, McWha would likely have said so.

Furthermore, one of skill in the art would not have been motivated to manufacture the epidural needle of McWha from plastic. Without any indication that McWha's epidural needle could be manufactured from plastic, or some other flexible material, one of ordinary skill would have thought that steel is preferred precisely because it is inflexible; *i.e.*, steel makes an excellent cutting tool. Even the plastic cannula of Smith requires a separate "introducer" to cut and pierce the patient before placement of the cannula. Smith, at col. 3, lines 22-25. Regardless of whether the plastic cannula of Smith would provide any benefits to the needle set of McWha due to its self-lubricating properties, one of skill in the art would not have had a reason to manufacture a plastic needle to pierce and cut the skin and underlying tissue of a patient at the site of catheter insertion, because plastic does not form piercing and cutting elements as well as, for example, steel.

Appellant respectfully notes that, even if plastic materials exist that perform the piercing and cutting function required by McWha's epidural needle as well as steel, one of skill in the art would not expect such materials to be "flexible." Rather, it would be expected that

[1] This is the element of McWha cited by the Examiner to be analogous to the claimed "flexible needle catheter." *See, e.g.*, Final Office Action of August 19, 2011, at p. 3 (flexible needle catheter is McWha element 12).

such plastics make better piercing and cutting instruments than other plastics precisely because they are more rigid.

The Examiner has previously asserted that "every medical instrument, especially those comprised of a thin tube of any material, will have some degree of flexibility." Final Office Action of March 24, 2009, at page 3 (regarding an introducer described in U.S.). Appellant does not contest the fact that even rigid materials such as steel, when subjected to large forces, will exhibit some amount of deformity before they break. Furthermore, the claimed flexible needle catheters are expressly recited to comprise "sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation." It would be appreciated by one of ordinary skill in the art that not all materials that are "flexible" in the very broad sense previously suggested by the Examiner (and indeed very few of them) are capable of the recited transverse flexibility. Indeed, it is respectfully submitted that steel, and a great many plastics, do not possess the requisite transverse flexibility.

The Examiner also asserts that the spinal needle[2] of McWha "is extended from the position shown in Figure 2 to that shown in Figure 3 and as such, as the opening passes the leading edge, they are contiguous." Final Office Action of August 19, 2011, at p. 4. Appellant respectfully submits that this assertion by the Examiner is error.

As set forth, *supra*, as the spinal needle of McWha is advanced beyond the open distal end of the epidural needle, its openings will not be the contiguous with the leading edge of the epidural needle. Rather, the openings of the spinal needle will be contiguous with an edge defined by an intersection between the surface of the bevel and the inner surface of the epidural needle defining the hollow bore. McWha, at col. 4, lines 57-65; col. 5, lines 16-18 and 25-29; and FIGS. 2-4a. This contiguous edge in McWha is not the "leading edge" of the assembly. Referring to FIG. 4 of McWha, the contiguous edge is represented as element 34, and the leading edge as the needle is advanced is the edge at the furthest distal end of element 12, the

[2] Appellant notes that the Examiner states that the "flexible needle catheter" is extended. However, this appears to be an error, because the Examiner asserts that it is element 12 of McWha that is a "flexible needle catheter," and that it is element 22 that is a "support needle." Final Office Action of August 19, 2011, at p. 3. In McWha, it is element 22 (the alleged support needle) that is extended. McWha, *e.g.*, at FIG. 3.

epidural needle. Id., at FIG. 4. The exact location of this edge is used to measure the bevel angle (Θ) in FIG. 4. Id.

Appellant acknowledges the Examiner's duty under the examination rules of the U.S.P.T.O. to give claim 1 its broadest reasonable interpretation. *See* M.P.E.P. § 2111. However, this broadest reasonable interpretation must be consistent with the Specification as it would be interpreted by one of ordinary skill in the art. Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005). Appellant respectfully asserts that the Examiner's interpretation of the term "contiguous" (*i.e.*, that the opening is contiguous with the leading edge because it "passes" the leading edge during extension; *see* Final Office Action of August 19, 2011, at p. 4) is not consistent with the meaning one of ordinary skill in the art would give this term in view of the Specification. As set forth, *supra*, a person of ordinary skill in the art would interpret the meaning of "contiguous," with regard to a support needle opening, in view of the Specification to describe a relationship where the position of the opening is connected to the reference edge without a break or interruption; *e.g.*, where the tip of the epidural needle is "tapered into a curve to blend smoothly into the edge of support needle." Specification, at **[0037]**.

Reversal of the rejection is courteously solicited.

(2) Argument supporting claims 3-6, 8, 9, 12, 14, 15, and 32

Solely for the purpose of this appeal, claims 3-6, 8, 9, 12, 14, 15, and 32 will not be separately argued, and will stand or fall with claim 1. Appellant respectfully notes that a dependent claim is obvious only if the independent claim from which it depends is obvious. *See* In re Fine, 837 F.2d 1071, 1076 (Fed. Cir. 1988).

Reversal of the rejections is courteously solicited.

(3) Separate argument supporting claim 16

(i) Claim construction

Flexible needle: Claim 16 recites that the claimed flexible needle catheter assembly comprises, *inter alia*, "a flexible needle... made of a material that has... sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom."

Thus, claim 16 is drawn specifically to needle catheter assemblies that comprise a needle made of a material that has the recited flexibility. As explained in the Specification,

> Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from the patient. A flexible needle desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body.
>
> Id., at **[0036]**.

Claim 16 expressly recites these properties of the claimed flexible plastic needle catheters, as set forth, *supra*. Accordingly, claim 16 is not drawn to assemblies comprising a needle that may be described as "flexible," but which lacks the ability to deform and accommodate patient motion. Likewise, claim 16 is not drawn to assemblies comprising a needle that is inflexible.

Flexible needle "carried exterior to" support needle: Claim 16 further recites that the flexible needle has an internal bore, and that the claimed needle assembly comprises "a support needle having... a pencil point non-cutting piercing point at a distal end... wherein [the] flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for [] inserting."

FIG. 1 of the as-filed application depicts the support needle, and **FIG. 3** depicts the internal bore defined by the flexible needle. Moreover, the Specification describes for one of skill in the art the specific meaning of the element, "carried exterior to," which defines the relationship between the claimed support needle and the flexible needle. For example, the Specification describes the "[p]lacement of the flexible needle (*i.e.*, the flexible needle catheter) ***over*** the inserting needle (*i.e.*, the support needle)," and explains that this arrangement "allows a larger diameter flexible needle to be inserted," as compared to prior spinal catheters. Id., at

[0011] (emphasis added). Likewise, the Specification explains, "An assembly typically includes a support needle, [and] a flexible needle slidably ***mounted on*** the support needle." Id., at **[0015]** (emphasis added).

The flexible needle and support needle perform specific functions in the claimed assembly, and the claimed configuration is essential to achieving the benefits of the assembly. For example, the flexible needle remains after the support needle has been withdrawn through the internal bore of the flexible needle, and because the flexible needle is carried exterior to the support needle, it has a larger diameter that allows better flow of CSF and medicating agents. Id., *e.g.*, at **[0011]** and **[0021]**. Thus, it would be appreciated by one of ordinary skill in the art that the flexible needle that is carried on the exterior of the support needle must be the needle that remains to comprise the spinal catheter following insertion, while the support needle must be the needle that performs piercing during insertion and then is subsequently withdrawn through the remaining flexible needle (catheter).

(ii) Analysis

Claim 16 is not rendered obvious by McWha and Smith, because these references, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle. To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim).

1. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible spinal needle assembly comprising a flexible needle having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," wherein the flexible needle is the element of the assembly that remains after placement to function as the catheter. Thus, the cited combination of references does not yield the claimed subject matter.

As set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), McWha does not describe a flexible needle catheter. In contrast to the claimed plastic flexible needle catheters, the epidural needle cannula of McWha (which is the element asserted by the Examiner to correspond to the claimed needle catheters) is preferably formed from stainless steel, which is the only exemplary material identified in McWha from which it may be fabricated. McWha, at col. 7, line 67, to col. 8, line 2. In any case, the cannula of McWha must be of sufficient composition to pierce and cut the skin and tissue of a patient. Id., at col. 4, lines 57-65; col. 5, lines 7-16; and FIGs. 4 and 4a.

One of ordinary skill in the art would understand that fabricating the needle cannula of McWha to have sufficient transverse flexibility to deform and accommodate patient motion after insertion would render the epidural needle and cannula unsatisfactory for its intended purpose; *i.e.*, if the needle cannula deformed and accommodated patient motion, it would not be expected to have sufficient rigidity to hold its shape and penetrate and cut the patient's tissue when pressed against the patient's tissue. Neither does Smith describe a flexible cannula that does not need to be introduced through a pre-formed passage. *See* Smith, *e.g.*, at col. 3, lines 19-33. If one of ordinary skill in the art would have considered Smith to determine whether to manufacture the epidural needle of McWha from a flexible material, such person would if anything have been dissuaded, since Smith's plastic cannula can only be inserted into a patient following an extra piercing/cutting step. *See* Id.

Thus, the needle set of McWha would be understood to be inflexible, and if it were modified to have a flexible needle cannula, the needle set would no longer be expected to function to establish access of delivered medicaments to the epidural space.

2. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle, as claimed. Thus, the cited combination of references does not yield the claimed subject matter.

McWha does not describe a needle catheter that is carried exterior to a piercing support needle. Rather, McWha describes that it is the element referred to therein as the spinal needle (element 22) that is used as the catheter; *i.e.*, medicament flows into the subarachnoid

space through the spinal needle. McWha, *e.g.*, at col. 5, lines 9-10 and 33-42. The spinal needle of McWha is not carried exterior to the second needle (epidural needle 12) in the assembly. The spinal needle of McWha is disposed within the epidural needle. Id., *e.g.*, at FIGs. 2 and 3.

Because the spinal needle of McWha must be disposed ***within*** the epidural needle, the spinal needle catheter must necessarily have a smaller diameter than the epidural needle that is used to pierce and cut the patient's skin and tissue. Therefore, the same sized penetration cannot accommodate as large a catheter when using the assembly of McWha as when using the assembly of claim 16. Thus, McWha cannot achieve the particular benefits of claim 16, for example, as recited in the Specification at **[0011]** and **[0021]**.

Smith does not supply this element of claim 1 that is missing from McWha. Smith does not describe a catheter at all, other than in the context of an element to be inserted through the described cannula after use of the cannula and stylet system. Smith, at col. 3, lines 29-33; and col. 5, lines 15-20.

For the foregoing reasons, the cited references, when viewed as a whole according to the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle.

(iii) Examiner's position

While the Examiner asserts that McWha describes a flexible spinal needle assembly comprising a flexible needle (Final Office Action of August 16, 2011, at p. 6; citing epidural needle 12 of McWha), the Examiner has not explained with particularity why the epidural needle of McWha is flexible. Moreover, the Examiner has not asserted at all that the epidural needle of McWha has sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom, or explained how Smith could supply this otherwise absent element from McWha[3].

[3] Appellant notes that the Examiner has discussed plastic composition with regard to claim 16, but Appellant further notes that plastic is not specified as the material for the flexible needle in claim 16.

Appellant respectfully submits that the Examiner's assertion that McWha describes a flexible epidural needle is in error. Moreover, Appellant respectfully submits that the failure of the Examiner to consider the recited flexibility of the claimed flexible needles is in error.

The Examiner asserts that McWha describes a flexible needle that is "carried exterior to [the] support needle." Id., at page 6 (citing McWha, at FIG. 3). The Examiner further asserts that the epidural needle of McWha (element 12) is a flexible needle as presently claimed, and that the spinal needle of McWha (element 22) is a support needle as claimed. Final Office Action of August 16, 2011, at page 6. However, while the epidural needle of McWha is carried exterior to the support needle therein, the epidural needle of McWha does not properly correspond to the claimed flexible needle, because the epidural needle of McWha is not used as a catheter.

Claim 16 explicitly recites that in a second condition of the claimed assembly, the "support needle [is] removed from within [the] bore of [the] flexible needle catheter." Thus, one of ordinary skill in the art would understand that the flexible needle of claim 16 is the catheter that remains to provide medicament to the patient after use of the assembly. In contrast, the epidural needle of McWha is used to initially penetrate the skin of the patient and cut through the underlying tissue. McWha, at col. 5, lines 7-16. It is the spinal needle of McWha that functions as a catheter in the described assembly. Id., at col. 5, lines 33-42.

When McWha is properly viewed as a whole, and compared with the subject matter of claim 16 as a whole, Appellant respectfully submits that it is clear the two needles of each are not able to be substituted in the simple manner suggested by the Examiner, where the epidural needle of McWha is used as the claimed flexible needle and the spinal needle of McWha is used as the claimed support needle. When viewed as a whole, there are two needles in each of claim 16 and McWha: one needle that penetrates the skin of the patient, and another needle that serves as a catheter for accessing the subarachnoid space. The penetrating needle is carried exterior to the catheter needle in McWha, while in claim 16 the situation is the inverse of this relationship. And, it is precisely this arrangement that provides benefits of the claimed invention. *See* Specification, *e.g.*, at **[0011]** and **[0021]**.

In view of the foregoing, Appellant respectfully submits that it was error for the Examiner to find that McWha describes a needle assembly comprising a flexible needle, as claimed in claim 16, carried exterior to a support needle, as claimed in claim 16.

Reversal of the rejection is courteously solicited.

(4) Argument supporting claims 17, 18, 20, 21, and 23

Solely for the purpose of this appeal, claims 17, 18, 20, 21, and 23 will not be separately argued, and will stand or fall with claim 16. Appellant respectfully notes that a dependent claim is obvious only if the independent claim from which it depends is obvious. *See* In re Fine, 837 F.2d, at 1076.

Reversal of the rejections is courteously solicited.

(5) Separate argument supporting claim 25

Claim 25 recites:

A flexible spinal needle comprising:

a support needle having a pencil point, non-cutting piercing tip, said support needle defining an interior lumen and an opening, said opening communicating said interior lumen with the exterior of said support needle;

a ***flexible needle body*** comprising an elongated hollow tube and made of a material that has a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body, but also possessing ***sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom***, said flexible needle body configured to be removeably and slidably mounted on an exterior of said support needle, said flexible needle body defining a leading edge, ***said leading edge being positioned contiguous to said opening of said support needle***; and

a flexible kink sleeve disposed on a portion of said flexible needle body, said flexible

kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent beyond a flexible structural resilience thereof during use

wherein said support needle is positionable in two conditions relative to said flexible needle body; in a first condition said flexible needle body is mounted on said exterior of said support needle, said support needle being positioned with said first end of said support needle extending beyond said leading edge of said flexible needle body, and in a second condition said support needle is removed from physical contact with said flexible needle body.

As set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle comprising a flexible needle body having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle body is mounted on the exterior of a support needle having an opening, and the leading edge of the flexible needle body is "positioned contiguous to [the] opening of [the] support needle," as claimed in claim 25. Thus, the cited combination of references does not yield the claimed subject matter.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim).

Also as set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha out of a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed in claim 25.

To establish a prima facie case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine

the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

1. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle body having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom."

McWha does not describe a flexible needle body, let alone a needle body with "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom." In contrast to the claimed flexible needle bodies, the epidural needle cannula of McWha (which is the element asserted by the Examiner to correspond to the claimed needle catheters) is preferably formed from stainless steel, which is the only exemplary material identified in McWha from which it may be fabricated. McWha, at col. 7, line 67, to col. 8, line 2. In any case, the cannula of McWha must be of sufficient composition to pierce and cut the skin and tissue of a patient. Id., at col. 4, lines 57-65; col. 5, lines 7-16; and FIGs. 4 and 4a. Thus, the needle set of McWha would be understood to be inflexible.

2. A person of ordinary skill in the art at the time of invention would not have been motivated to modify the preferably steel needle cannula of McWha (McWha, at col. 7, line 67, to col. 8, line 2) to be fabricated of a material having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," as recited in claim 25.

McWha describes that a bevel of the preferably steel needle defines what appears to be a cutting point at a leading edge on a side of the epidural needle comprising the needle cannula. Id., at col. 4, lines 57-65; and FIGs. 4 and 4a. Additionally, McWha teaches that the epidural needle comprising the needle cannula is advanced into the epidural space ***through the skin*** of a patient. Id., at col. 5, lines 7-16.

One of ordinary skill in the art would understand that fabricating the needle cannula of McWha to have sufficient transverse flexibility to deform and accommodate patient motion after insertion would render the epidural needle and cannula unsatisfactory for its intended purpose; *i.e.*, if the needle cannula deformed and accommodated patient motion, it would not be

expected to have sufficient rigidity to hold its shape and penetrate and cut the patient's tissue when pressed against the patient's tissue. Neither does Smith describe a flexible cannula that does not need to be introduced through a pre-formed passage. *See* Smith, *e.g.*, at col. 3, lines 19-33. If one of ordinary skill in the art would have considered Smith to determine whether to manufacture the epidural needle of McWha from a flexible material, such person would if anything have been dissuaded, since Smith's plastic cannula can only be inserted into a patient following an extra piercing/cutting step. *See* Id.

Thus, if the needle set of McWha were modified to have a flexible needle cannula, it would have been expected that the needle set would no longer function to establish access of delivered medicaments to the epidural space.

3. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle body removably and slidably mounted on the exterior of a support needle, wherein the flexible needle body has a "leading edge [] positioned contiguous to [the] opening of [the] support needle," as is recited by the claim.

McWha does not describe a spinal needle (asserted by the Examiner to correspond to the claimed support needle) that has an opening positioned contiguous to the leading edge of the flexible needle body. Rather, as the spinal needle of McWha is advanced beyond the open distal end of the epidural needle, its openings will be contiguous with an edge defined by an intersection between the surface of the bevel and the ***inner*** surface of the epidural needle defining the hollow bore. McWha, at col. 4, lines 57-65; col. 5, lines 16-18 and 25-29; and FIGS. 2-4a. However, this edge that is contiguous with the spinal needle openings in McWha is not the "leading edge" of the epidural needle, because the edge defined by the intersection between the surface of the bevel and the ***outer*** surface of the epidural needle "leads" as the spinal epidural needle set is advanced into the patient. Id.

Smith does not supply this element of claim 1 that is missing from McWha. Smith describes a stylet having a pointed end that appears to block access to the bore of the cannula, because spinal fluid is aspirated through the cannula only after removal of the stylet from the cannula. Smith, at col. 5, lines 8-11.

Thus, the cited combination of references does not yield the claimed subject matter

for this additional reason.

Reversal of the rejection is courteously solicited.

(6) Separate argument supporting claim 27

Claim 27 recites:

A flexible spinal needle assembly comprising:

a support needle comprising a first end defining a pencil point, non-cutting piercing point, and a hollow bore with an opening proximate said first end allowing access to said bore; and

a flexible needle removably and slidably mounted on an exterior portion of said support needle such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, said flexible needle made of a material having a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body, but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom and having a leading edge positioned contiguous to the opening of the support needle after insertion, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle, said flexible needle defining a lumen therein for transporting a medicinal agent;

wherein said support needle is positionable in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said first end of said support needle extending beyond said leading edge of said flexible needle, said non-cutting piercing point and said opening being positioned beyond said leading edge, the opening being positioned contiguous to the leading edge, and in a second condition said support needle being removed from physical contact with said flexible needle.

As set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. §

103(a), McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle assembly comprising a flexible needle having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle body is mounted on an exterior portion of a support needle. Neither do either or both of the references teach or fairly suggest a flexible spinal needle assembly comprising a support needle with a pencil point, non-cutting piercing point and an opening, wherein the non-cutting piercing point and the opening are "positioned contiguous to the leading edge" of the flexible needle in the same condition wherein the opening is "positioned beyond said leading edge," as claimed in claim 27. Thus, the cited combination of references does not yield the claimed subject matter.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim).

Also as set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha out of a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed in claim 27.

To establish a prima facie case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

1. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom."

McWha does not describe a flexible needle, let alone a needle with "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient

irritation therefrom." In contrast to the claimed flexible needles, the epidural needle cannula of McWha (which is the element asserted by the Examiner to correspond to the claimed flexible needles) is preferably formed from stainless steel, which is the only exemplary material identified in McWha from which it may be fabricated. McWha, at col. 7, line 67, to col. 8, line 2. In any case, the cannula of McWha must be of sufficient composition to pierce and cut the skin and tissue of a patient. Id., at col. 4, lines 57-65; col. 5, lines 7-16; and FIGs. 4 and 4a. Thus, the needle set of McWha would be understood to be inflexible.

2. A person of ordinary skill in the art at the time of invention would not have been motivated to modify the preferably steel needle cannula of McWha (McWha, at col. 7, line 67, to col. 8, line 2) to be fabricated of a material having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," as recited in claim 27.

McWha describes that a bevel of the preferably steel needle defines what appears to be a cutting point at a leading edge on a side of the epidural needle comprising the needle cannula. Id., at col. 4, lines 57-65; and FIGs. 4 and 4a. Additionally, McWha teaches that the epidural needle comprising the needle cannula is advanced into the epidural space ***through the skin*** of a patient. Id., at col. 5, lines 7-16.

One of ordinary skill in the art would understand that fabricating the needle cannula of McWha to have sufficient transverse flexibility to deform and accommodate patient motion after insertion would render the epidural needle and cannula unsatisfactory for its intended purpose; *i.e.*, if the needle cannula deformed and accommodated patient motion, it would not be expected to have sufficient rigidity to hold its shape and penetrate and cut the patient's tissue when pressed against the patient's tissue. Neither does Smith describe a flexible cannula that does not need to be introduced through a pre-formed passage. *See* Smith, *e.g.*, at col. 3, lines 19-33. If one of ordinary skill in the art would have considered Smith to determine whether to manufacture the epidural needle of McWha from a flexible material, such person would if anything have been dissuaded, since Smith's plastic cannula can only be inserted into a patient following an extra piercing/cutting step. *See* Id.

Thus, if the needle set of McWha were modified to have a flexible needle, it would have been expected that the needle set would no longer function to establish access of delivered medicaments to the epidural space.

3. McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible spinal needle assembly comprising a support needle with a pencil point, non-cutting piercing point and an opening, wherein the non-cutting piercing point and the opening are "positioned contiguous to the leading edge" of the flexible needle in the same condition wherein the opening is "positioned beyond said leading edge," as is recited by claim 27.

McWha does not describe a spinal needle (asserted by the Examiner to correspond to the claimed support needle) that has an opening positioned contiguous to the leading edge of the flexible needle body, particularly in the same condition wherein the opening is positioned beyond the leading edge. Rather, when the spinal needle of McWha has been advanced beyond the open distal end of the epidural needle, its openings will be contiguous with an edge defined by an intersection between the surface of the bevel and the ***inner*** surface of the epidural needle defining the hollow bore. McWha, at col. 4, lines 57-65; col. 5, lines 16-18 and 25-29; and FIGS. 2-4a. However, this edge that is contiguous with the spinal needle openings in McWha is not the "leading edge" of the epidural needle, because the edge defined by the intersection between the surface of the bevel and the ***outer*** surface of the epidural needle "leads" as the spinal epidural needle set is advanced into the patient. Id.

Smith does not supply this element of claim 1 that is missing from McWha. Smith describes a stylet having a pointed end that appears to block access to the bore of the cannula, because spinal fluid is aspirated through the cannula only after removal of the stylet from the cannula. Smith, at col. 5, lines 8-11.

Thus, the cited combination of references does not yield the claimed subject matter for this additional reason.

Reversal of the rejection is courteously solicited.

(7) **Separate argument supporting claim 28**

Claim 28 recites:

The flexible spinal needle assembly of claim 27 wherein the flexible needle comprises a medical grade plastic material and a tip extending axially from the flexible needle body of said flexible needle of substantial extent to be further extendable into the dura mater upon extraction of said support needle.

As set forth, *supra*, in regard to the Examiner's rejection of claim 27 under 35 U.S.C. § 103(a), McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle assembly comprising a flexible needle having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle body is mounted on an exterior portion of a support needle. Neither do either or both of the references teach or fairly suggest a flexible spinal needle assembly comprising a support needle with a pencil point, non-cutting piercing point and an opening, wherein the non-cutting piercing point and the opening are "positioned contiguous to the leading edge" of the flexible needle in the same condition wherein the opening is "positioned beyond said leading edge," as claimed in claim 28. Thus, the cited combination of references does not yield the claimed subject matter.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim).

Also as set forth, *supra*, in regard to the Examiner's rejection of claim 27 under 35 U.S.C. § 103(a), there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha out of a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed in claim 28.

To establish a *prima facie* case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Claim 28 is not rendered obvious by the combination of McWha and Smith for the further reason that these references, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a "flexible needle compris[ing] a medical grade plastic material" as claimed.

As set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), McWha does not describe a plastic flexible needle catheter, and this is a fact that has been recognized by the Examiner. Final Office Action of August 19, 2011, at p. 10. In contrast to the claimed plastic flexible needles, both of the needle cannulas of McWha (including the epidural needle cannula asserted by the Examiner to correspond to the claimed plastic, flexible needles) are preferably formed from stainless steel, which is the only exemplary material identified in McWha from which it may be fabricated. McWha, at col. 7, line 67, to col. 8, line 2.

The non-plastic nature of the material used to fabricate McWha's cannulas is emphasized by the context in which it appears. In the paragraph of McWha describing their preferable stainless steel composition, other elements of McWha's needle set are explicitly recited to be able to be constructed from plastic. For example, McWha states that "[n]eedle hubs may be formed from thermoplastic materials" (Id., at col. 7, lines 63-64), and "[o]ther components (besides the cannula and spinal needle) of the several embodiments of the assembly of the invention such as spacer and threaded washer may also be formed from thermoplastics" (Id., at col. 8, lines 2-4). Thus, the epidural needle and spinal needle are expressly omitted from the set of assembly components in McWha that may be fabricated from plastic.

The express and inherent teachings of Smith are not such that they may be combined with the inflexible, steel cannula of McWha, using only the knowledge and skill of one of ordinary skill in the art at the time of the invention, to yield a plastic flexible needle having the attributes of those claimed. While Smith describes a cannula that comprises a plastic "elongated

member" with "a greater self-lubricating property" than steel (Smith, at col. 3, lines 12-22), it is the ***spinal catheter*** of Smith's system, and not its plastic cannula, that is anchored to the patient (Id., at col. 5, lines 19-20) and through which medication is delivered (Id., at col. 3, lines 29-33). In contrast, the presently claimed flexible needle "convey[s] medicating agent" to a patient through its hollow bore, while providing all the benefits of its flexibility and dimensions, which are not properties delivered to the removable positioning cannula of Smith by its plastic composition.

Accordingly, McWha and Smith do not render obvious a flexible spinal needle assembly comprising a plastic, flexible needle, as claimed, with all of its properties and advantages.

For the foregoing reasons, the cited combination of references does not yield the subject matter of claim 28.

Reversal of the rejection is courteously solicited.

(8) Separate argument supporting claim 29

Claim 29 recites:

The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle.

As set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading edge of the plastic, flexible needle catheter, as claimed. Moreover, there would have been no reason or motivation at the time the invention was made for one of

ordinary skill in the art to fabricate the needle catheter of McWha out of a flexible plastic material.

Claim 29 is not rendered obvious by the combination of McWha and Smith for the further reason that these references, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle assembly comprising a flexible needle catheter with a first end that is "tapered into a curve to blend smoothly into the outer surface of [the] support needle," as recited in claim 29. Thus, the cited combination of references does not yield the claimed subject matter for this additional reason.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

The Examiner asserts that McWha describes a "flexible needle catheter [that] is tapered into a curve to blend smoothly into the outer surface of [the] support needle." Final Office Action of August 19, 2011, at page 5. Appellant respectfully submits that the Examiner is incorrect. Not only does McWha not describe a "flexible" needle catheter, McWha does not describe a catheter that is tapered to blend smoothly into the outer surface of the support needle. The Examiner cites FIG. 4a of McWha as support for the asserted disclosure. Id. FIG. 4a of McWha does indeed depict the epidural needle of the assembly described therein, but it does not contain any representation of the spinal needle. McWha, at FIG. 4a. Rather, FIG. 6 shows the epidural needle tip design of FIP. 4a with the spinal needle disposed therein. Id., at FIG. 6. As can clearly be seen from FIG. 6, the end of the epidural needle of McWha does not blend smoothly into the outer surface of the support needle; there is a prominent interruption between the surfaces at the leading edge of the epidural needle. *See* Id.

For the foregoing reasons, the cited combination of references does not yield the

subject matter of claim 29.

Reversal of the rejection is courteously solicited.

(9) Separate argument supporting claim 35

Claim 35 recites:

The flexible spinal needle assembly of Claim 16 wherein said leading edge of the flexible needle is arranged relative to said support needle such that said leading edge of the flexible needle is positioned contiguous to the opening of the support needle after an insertion of said leading edge into the patient's body.

As set forth, *supra*, in regard to the Examiner's rejection of claim 16 under 35 U.S.C. § 103(a), McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle. Thus, claim 35 is not obvious for at least the reason that the combination and modification of the cited references does not yield the subject matter claimed in claim 35.

Moreover, for the reasons set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a), McWha and Smith, either alone or in combination, do not teach or fairly suggest a flexible needle carried exterior to a support needle "such that said leading edge of the flexible needle is positioned contiguous to the opening of the support needle after an insertion of said leading edge into the patient's body," as is recited by the claim.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim).

McWha does not describe a spinal needle (asserted by the Examiner to correspond to the claimed support needle) that has an opening positioned contiguous to the leading edge of the flexible needle catheter. As the spinal needle of McWha is advanced beyond the open distal end of the epidural needle, its openings will be contiguous with an edge defined by an intersection between the surface of the bevel and the ***inner*** surface of the epidural needle defining the hollow bore. McWha, at col. 4, lines 57-65; col. 5, lines 16-18 and 25-29; and FIGS. 2-4a. However, this edge that is contiguous with the spinal needle openings in McWha is not the "leading edge" of the epidural needle, because the edge defined by the intersection between the surface of the bevel and the ***outer*** surface of the epidural needle "leads" as the spinal epidural needle set is advanced into the patient. Id.

Smith does not supply this element of claim 35 that is missing from McWha. Smith describes a stylet having a pointed end that appears to block access to the bore of the cannula, because spinal fluid is aspirated through the cannula only after removal of the stylet from the cannula. Smith, at col. 5, lines 8-11.

Thus, the cited combination of references does not yield the claimed subject matter for this additional reason.

Reversal of the rejection is courteously solicited.

B) Claims 30 and 31 were not obvious to one of ordinary skill in the art at the time the invention was made, notwithstanding McWha; Smith; and Gribbons.

(1) Separate argument supporting claim 30

Claim 30 recites:

The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is reinforced with a flat ribbon internal spring disposed within a wall of said flexible needle.

To form the basis of the Examiner's rejection of claim 30, McWha and Smith are erroneously asserted by the Examiner to describe the elements set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a). Final Office Action of August 19, 2011, at page 11.

However, as previously demonstrated, McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading edge of the plastic, flexible needle catheter, as claimed. Moreover, there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the needle catheter of McWha out of a flexible plastic material, as claimed in claim 30.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover to establish a *prima facie* case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Gribbons describes a catheter with a catheter shaft that includes a proximal shaft, a distal shaft, and a transition section. Gribbons, at **[0041]** and FIG. 1. The transition section is described as having a distal end defined by a transition means, which is depicted as a spiral helix of metal wire or ribbon, twisted to form a coil. Id., at **[0041]** and **[0060]**. Gribbons is asserted by the Examiner only to allegedly describe "a flat metal ribbon or band (140) within the body of a catheter in order to provide support." Final Office Action of August 19, 2011, at page 11.

However, even if this assertion of the Examiner is correct, Gribbons does not provide

the knowledge or motivation for one of ordinary skill in the art at the time of the invention to supply the elements otherwise missing from the combination of McWha and Smith. To wit, Gribbons does not describe or suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading edge of the plastic, flexible needle catheter, as recited in claim 30.

Thus, the cited combination of references does not yield the subject matter of claim 30.

Reversal of the rejection is courteously solicited.

(2) Argument supporting claim 31

Solely for the purpose of this appeal, claim 31 will not be separately argued, and will stand or fall with claim 30. Appellant respectfully notes that a dependent claim is obvious only if the independent claim from which it depends is obvious. *See* In re Fine, 837 F.2d, at 1076.

Reversal of the rejections is courteously solicited.

C) Claims 34, 36, 37, and 38 were not obvious to one of ordinary skill in the art at the time the invention was made, notwithstanding McWha; Smith; and Klein.

(1) Separate argument supporting claim 34

Claim 34 recites:

The flexible needle catheter assembly of Claim 1 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

To form the basis of the Examiner's rejection of claim 34, McWha and Smith are erroneously asserted by the Examiner to describe the elements set forth, *supra*, in regard to the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a). Final Office Action of August 19,

2011, at page 11.

However, as previously demonstrated with regard to claim 1, McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading edge of the plastic, flexible needle catheter, as claimed. Moreover, there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the needle catheter of McWha from a flexible plastic material, as claimed in claim 34.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover, to establish a *prima facie* case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Klein describes a stainless steel infiltration cannula comprising a distal end with a closed tip (Klein, at **[0031]**; **[0034]**; and FIGs. 1 and 2), and a plastic infiltration cannula that can be blunt tipped with a metal stylet tip covered by the rounded tip of the plastic cannula (Id., at **[0031]**; **[0037]**; and FIGs. 3 and 4) or open-ended with the stylet extending a short distance past the end of the plastic cannula (Id., at **[0037]**). Klein is asserted by the Examiner only to allegedly describe "a cannula assembly having a flexible cannula and stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular leading edge) in the case that an incision already exists for insertion." Final Office Action of August 19, 2011, at page 11.

However, even if this assertion of the Examiner were correct, Klein does not provide the knowledge or motivation for one of ordinary skill in the art at the time of the invention to

supply the elements otherwise missing from the combination of McWha and Smith. To wit, Klein does not describe or suggest a spinal needle catheter assembly comprising a plastic, flexible needle catheter that contains a support needle in the hollow bore of the plastic, flexible needle catheter, wherein the support needle comprises an opening that is positioned contiguous to the leading edge of the plastic, flexible needle catheter, as recited in claim 34.

Thus, the cited combination of references does not yield the subject matter of claim 34.

Furthermore, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify McWha such that "a plane containing said leading edge is positioned ***perpendicularly to a longitudinal axis*** of [the] needle assembly," as claimed. McWha teaches that a bevel of the epidural needle defines a cutting point at a leading edge on a side of the epidural needle. McWha, at col. 4, lines 57-65; col. 5, lines 25-29; and FIGS. 4 and 4a. McWha further teaches that the epidural needle is advanced into the epidural space through the skin, and thus must be capable of forming an incision or penetration site. Id., at col. 5, lines 7-16. Forming the epidural needle of McWha such that the plane containing the leading edge is perpendicular to a longitudinal axis of the epidural needle would render the epidural needle unsatisfactory for its intended purpose of cutting through the skin of a patient to introduce the spinal epidural needle set into the epidural space, because such a modification would render the epidural needle blunt. *See* Id., at col. 5, lines 7-16.

Accordingly, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify the epidural needle taught in McWha to comprise all the elements recited in claim 34 because forming the tip of the epidural needle to be blunt would render the epidural needle unsatisfactory for cutting through the skin of a patient. Appellant respectfully submits that this is an additional reason that the obviousness rejection of claim 34 is in error.

Reversal of the rejection is courteously solicited.

(2) Separate argument supporting claim 36

Claim 36 recites:

The flexible needle catheter assembly of Claim 16 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

To form the basis of the Examiner's rejection of claim 36, McWha and Smith are erroneously asserted by the Examiner to describe the elements set forth, *supra*, in regard to the Examiner's rejection of claim 16 under 35 U.S.C. § 103(a). Final Office Action of August 19, 2011, at page 11.

However, as previously demonstrated with regard to claim 16, McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible needle catheter assembly comprising a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle, as claimed.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover, to establish a *prima facie* case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Klein describes a stainless steel infiltration cannula comprising a distal end with a closed tip (Klein, at **[0031]**; **[0034]**; and FIGs. 1 and 2), and a plastic infiltration cannula that can be blunt tipped with a metal stylet tip covered by the rounded tip of the plastic cannula (Id., at **[0031]**; **[0037]**; and FIGs. 3 and 4) or open-ended with the stylet extending a short distance past the end of the plastic cannula (Id., at **[0037]**). Klein is asserted by the Examiner only to allegedly describe "a cannula assembly having a flexible cannula and stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular

leading edge) in the case that an incision already exists for insertion." Final Office Action of August 19, 2011, at page 11.

However, even if this assertion of the Examiner were correct, Klein does not provide the knowledge or motivation for one of ordinary skill in the art at the time of the invention to supply the elements otherwise missing from the combination of McWha and Smith. To wit, Klein does not describe or suggest a flexible needle catheter assembly comprising a flexible needle that is used as the catheter, wherein the flexible needle is carried exterior to a piercing support needle, as recited in claim 36.

Thus, the cited combination of references does not yield the subject matter of claim 36.

Furthermore, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify McWha such that "a plane containing said leading edge is positioned ***perpendicularly to a longitudinal axis*** of [the] needle assembly," as claimed. McWha teaches that a bevel of the epidural needle defines a cutting point at a leading edge on a side of the epidural needle. McWha, at col. 4, lines 57-65; col. 5, lines 25-29; and FIGS. 4 and 4a. McWha further teaches that the epidural needle is advanced into the epidural space through the skin, and thus must be capable of forming an incision or penetration site. Id., at col. 5, lines 7-16. Forming the epidural needle of McWha such that the plane containing the leading edge is perpendicular to a longitudinal axis of the epidural needle would render the epidural needle unsatisfactory for its intended purpose of cutting through the skin of a patient to introduce the spinal epidural needle set into the epidural space, because such a modification would render the epidural needle blunt. *See* Id., at col. 5, lines 7-16.

Accordingly, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify the epidural needle taught in McWha to comprise all the elements recited in claim 36 because forming the tip of the epidural needle to be blunt would render the epidural needle unsatisfactory for cutting through the skin of a patient. Appellant respectfully submits that this is an additional reason that the obviousness rejection of claim 36 is in error.

Reversal of the rejection is courteously solicited.

(3) **Separate argument supporting claim 37**

Claim 37 recites:

The flexible needle catheter assembly of Claim 25 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

To form the basis of the Examiner's rejection of claim 37, McWha and Smith are erroneously asserted by the Examiner to describe the elements set forth, *supra*, in regard to the Examiner's rejection of claim 25 under 35 U.S.C. § 103(a). Final Office Action of August 19, 2011, at page 11.

However, as previously demonstrated with regard to claim 25, McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle comprising a flexible needle body having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle body is mounted on the exterior of a support needle having an opening, and the leading edge of the flexible needle body is "positioned contiguous to [the] opening of [the] support needle," as claimed in claim 37. Further, there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha from a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover, to establish a *prima facie* case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Klein describes a stainless steel infiltration cannula comprising a distal end with a closed tip (Klein, at **[0031]**; **[0034]**; and FIGs. 1 and 2), and a plastic infiltration cannula that can be blunt tipped with a metal stylet tip covered by the rounded tip of the plastic cannula (Id., at **[0031]**; **[0037]**; and FIGs. 3 and 4) or open-ended with the stylet extending a short distance past the end of the plastic cannula (Id., at **[0037]**). The cannula assembly of Klein is inserted through a previous incision, and thus does not need to pierce or form an incision. *See* Klein, at **[0004]**; see also Final Office Action of August 19, 2011, at pages 11-12. Klein is asserted by the Examiner only to allegedly describe "a cannula assembly having a flexible cannula and stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular leading edge) in the case that an incision already exists for insertion." Final Office Action of August 19, 2011, at page 11.

However, even if this assertion of the Examiner were correct, Klein does not provide the knowledge or motivation for one of ordinary skill in the art at the time of the invention to supply the elements and rationale otherwise missing from the combination of McWha and Smith. To wit, Klein does not describe or suggest a flexible spinal needle comprising a flexible needle body having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle body is mounted on the exterior of a support needle having an opening, and the leading edge of the flexible needle body is "positioned contiguous to [the] opening of [the] support needle." Likewise, the cannula of Klein that is inserted into a pre-existing incision would not have provided any reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha out of a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed.

Thus, the cited combination of references does not yield the subject matter of claim 37, and there would have been no motivation to arrive at the claimed subject matter.

Furthermore, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify McWha such that "a plane containing said leading edge is positioned ***perpendicularly to a longitudinal axis*** of [the] needle assembly," as claimed. McWha teaches that a bevel of the epidural needle defines a cutting point at a

leading edge on a side of the epidural needle. McWha, at col. 4, lines 57-65; col. 5, lines 25-29; and FIGS. 4 and 4a. McWha further teaches that the epidural needle is advanced into the epidural space through the skin, and thus must be capable of forming an incision or penetration site. Id., at col. 5, lines 7-16. Forming the epidural needle of McWha such that the plane containing the leading edge is perpendicular to a longitudinal axis of the epidural needle would render the epidural needle unsatisfactory for its intended purpose of cutting through the skin of a patient to introduce the spinal epidural needle set into the epidural space, because such a modification would render the epidural needle blunt. *See* Id., at col. 5, lines 7-16.

Accordingly, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify the epidural needle taught in McWha to comprise all the elements recited in claim 37 because forming the tip of the epidural needle to be blunt would render the epidural needle unsatisfactory for cutting through the skin of a patient. Appellant respectfully submits that this is an additional reason that the obviousness rejection of claim 37 is in error.

Reversal of the rejection is courteously solicited.

(4) Separate argument supporting claim 38

Claim 38 recites:

The flexible needle catheter assembly of Claim 27 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

To form the basis of the Examiner's rejection of claim 38, McWha and Smith are erroneously asserted by the Examiner to describe the elements set forth, *supra*, in regard to the Examiner's rejection of claim 27 under 35 U.S.C. § 103(a). Final Office Action of August 19, 2011, at page 11.

However, as previously demonstrated with regard to claim 27, McWha and Smith, either taken alone or in combination in view of the ordinary skill and creativity in the art, do not teach or fairly suggest a flexible spinal needle assembly comprising a flexible needle having

"sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle is mounted on an exterior portion of a support needle. Neither do either or both of the references teach or fairly suggest a flexible spinal needle assembly comprising a support needle with a pencil point, non-cutting piercing point and an opening, wherein the non-cutting piercing point and the opening are "positioned contiguous to the leading edge" of the flexible needle in the same condition wherein the opening is "positioned beyond said leading edge. Further, there would have been no reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha from a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed.

To render a claim obvious under 35 U.S.C. § 103(a), the cited references, or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention, must teach or suggest all of the elements of the claim. KSR Intern. Co., 550 U.S., at 418; In re Wilson, 424 F.2d, at 1385; *see also* Bausch & Lomb, 796 F.2d, at 449 (claimed invention as a whole includes every element of claim). Moreover, to establish a prima facie case of obviousness, a reason or motivation must have existed at the time of the invention for a person of ordinary skill in the art to modify or combine the known elements in the prior art as a whole to arrive at the claimed subject matter. KSR Intern. Co., 550 U.S., at 418.

Klein describes a stainless steel infiltration cannula comprising a distal end with a closed tip (Klein, at **[0031]**; **[0034]**; and FIGs. 1 and 2), and a plastic infiltration cannula that can be blunt tipped with a metal stylet tip covered by the rounded tip of the plastic cannula (Id., at **[0031]**; **[0037]**; and FIGs. 3 and 4) or open-ended with the stylet extending a short distance past the end of the plastic cannula (Id., at **[0037]**). The cannula assembly of Klein is inserted through a previous incision, and thus does not need to pierce or form an incision. *See* Klein, at **[0004]**; see also Final Office Action of August 19, 2011, at pages 11-12. Klein is asserted by the Examiner only to allegedly describe "a cannula assembly having a flexible cannula and stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular leading edge) in the case that an incision already exists for insertion."

Final Office Action of August 19, 2011, at page 11.

However, even if this assertion of the Examiner were correct, Klein does not provide the knowledge or motivation for one of ordinary skill in the art at the time of the invention to supply the elements and rationale otherwise missing from the combination of McWha and Smith. To wit, Klein does not describe or suggest a flexible needle having "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom," where the flexible needle is mounted on an exterior portion of a support needle, or a flexible spinal needle assembly comprising a support needle with a pencil point, non-cutting piercing point and an opening, wherein the non-cutting piercing point and the opening are "positioned contiguous to the leading edge" of the flexible needle in the same condition wherein the opening is "positioned beyond said leading edge. Likewise, the cannula of Klein that is inserted into a pre-existing incision would not have provided any reason or motivation at the time the invention was made for one of ordinary skill in the art to fabricate the catheter of McWha out of a material possessing "sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom," as claimed in claim 38.

Thus, the cited combination of references does not yield the subject matter of claim 38, and there would have been no motivation to arrive at the claimed subject matter.

Furthermore, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify McWha such that "a plane containing said leading edge is positioned ***perpendicularly to a longitudinal axis*** of [the] needle assembly," as claimed. McWha teaches that a bevel of the epidural needle defines a cutting point at a leading edge on a side of the epidural needle. McWha, at col. 4, lines 57-65; col. 5, lines 25-29; and FIGS. 4 and 4a. McWha further teaches that the epidural needle is advanced into the epidural space through the skin, and thus must be capable of forming an incision or penetration site. Id., at col. 5, lines 7-16. Forming the epidural needle of McWha such that the plane containing the leading edge is perpendicular to a longitudinal axis of the epidural needle would render the epidural needle unsatisfactory for its intended purpose of cutting through the skin of a

patient to introduce the spinal epidural needle set into the epidural space, because such a modification would render the epidural needle blunt. *See* Id., at col. 5, lines 7-16.

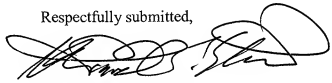
Accordingly, a person of ordinary skill in the art at the time of invention would not have been motivated by Smith and Klein to modify the epidural needle taught in McWha to comprise all the elements recited in claim 38 because forming the tip of the epidural needle to be blunt would render the epidural needle unsatisfactory for cutting through the skin of a patient. Appellant respectfully submits that this is an additional reason that the obviousness rejection of claim 38 is in error.

Reversal of the rejection is courteously solicited.

SUMMARY

For at least the foregoing reasons, when the claims are properly construed and compared with the references cited by the Examiner, it is clear that the combination of these references does not yield a flexible needle catheter assembly with all the expressly recited elements and advantages of those claimed. Nor would a person of ordinary skill at the time the invention was made have been motivated to achieve these advantages by supplying missing elements to the cited references and combining them in the manner suggested by the Examiner. Accordingly, Appellant respectfully requests reversal of the pending rejections.

Respectfully submitted,



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Enclosures: Claims Appendix;
Evidence Appendix; and
Related Proceedings Appendix

VIII. CLAIMS APPENDIX

1. A flexible spinal needle catheter assembly comprising:

a flexible needle catheter fabricated of plastic and having a sufficiently high tensile strength to maintain structural integrity during and after insertion into a patient's body and retraction therefrom, but also possesses sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce patient irritation therefrom, said flexible needle catheter defining a hollow bore for conveying medicating agent therethrough, said bore extending through a length of said flexible needle catheter, said flexible needle catheter having a proximal end which defines a leading edge;

a support needle releaseably secured to said flexible needle catheter, said support needle being removably disposed within said hollow bore of said flexible needle catheter, said support needle having a first end which defines a pencil point, non-cutting piercing point configured for penetrating the dura mater of a patient, said support needle having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly from a dura mater of a spine of a patient, subsequent to an insertion of said assembly through the dura mater, a puncture opening produced by said insertion being of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly within said dura mater, said support needle defining a hollow lumen which extends along a length of said support needle and an opening, defined proximate said first end, which communicates the environment with said lumen, said support needle being positionable in two conditions relative to said flexible needle catheter; in a first condition said support needle being positioned with said first end of said support needle being positioned outside of said bore of said flexible needle catheter, said non-cutting piercing point and said opening being positioned outside of said bore, the opening being positioned contiguous to the leading edge of the flexible needle catheter and in a second condition said support needle being removed from within said hollow bore of said flexible needle catheter, and

a solid stylet, releaseably secured within said lumen, said stylet being positioned in a first condition to preclude access from the environment to said lumen through said opening.

3. The flexible spinal needle assembly of claim 1, wherein said leading edge of said flexible needle catheter is configured and arranged to provide a feedback signal to indicate dural puncture.

4. The flexible spinal needle assembly of claim 1, wherein: a rear end of said support needle carries a support hub having a first attach structure; and a proximal end of said flexible needle carries a flexible needle hub having a second attach structure configured to removably attach to the first attach structure carried by said support hub.

5. The flexible spinal needle assembly of claim 4, wherein the first and second attach structures comprise a luer lock type connection.

6. The flexible spinal needle assembly of claim 4, wherein said flexible needle hub is configured for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element.

7. The flexible spinal needle assembly of claim 4, wherein said flexible needle hub is configured for attachment to medical fluid transfer equipment by an attachment structure to form a connection generally perpendicular to a direction of needle insertion.

8. The flexible spinal needle assembly of claim 1, wherein: a rear end of said support needle carries a support hub; and a proximal end of said flexible needle carries a flexible needle hub having a detach structure configured to detach the flexible needle hub from the support hub.

9. The flexible spinal needle assembly of claim 1, wherein: a proximal end of said flexible needle carries a flexible needle hub; and a rear end of said support needle carries a support hub having a detach structure configured to detach the flexible needle hub from the support hub.

12. The flexible spinal needle assembly of claim 1, wherein said flexible needle further comprises a force absorbing structure to prevent kinking when the flexible needle is overly flexed.

13. The flexible spinal needle assembly of claim 12, wherein said force absorbing structure comprises a ribbon spring.

14. The flexible needle assembly of claim 12, wherein said force absorbing structure comprises a flexible kink sleeve disposed on a portion thereof.

15. The flexible spinal needle assembly of claim 1, wherein said stylet is slidably mounted in said support needle.

16. A flexible spinal needle assembly for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, said flexible spinal needle assembly comprising:

a flexible needle having a leading edge, and made of a material that has a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body, but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom, said flexible needle defining an internal bore through a length thereof;

a support needle having a proximal end and a pencil point non-cutting piercing point at a distal end, said support needle being releaseably secured to said flexible needle to resist relative motion between a distal end of said flexible needle and said pencil point non-cutting piercing point during insertion of said flexible spinal needle assembly into a patient, the support needle defining an interior lumen and an opening, said opening being adapted to communicate the interior lumen with the exterior of said support needle;

wherein said flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for said inserting, and

wherein said support needle is positionable in two conditions relative to said flexible needle; in a first condition said support needle is positioned within said bore of said flexible needle with said distal end of said support needle being positioned outside of said internal bore of said flexible needle, said non-cutting piercing point and said opening being positioned outside of said bore; and in a second condition said support needle being removed from within said bore of said flexible needle catheter.

17. The flexible spinal needle assembly of claim 16, wherein said flexible needle has an exterior diameter configured such that withdrawal of said flexible needle from said dura mater, subsequent to insertion of the flexible needle assembly therethrough, permits said dura mater substantially to reseal a space formerly occupied by said flexible needle, and a tip and a flexible needle body of said flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of said support needle.

18. The flexible spinal needle assembly of claim 17, wherein: said proximal end of said support needle carries a support hub having a first attach structure; a proximal end of said flexible needle carries a flexible needle hub having a second attach structure configured to interface in removable interference with said first attach structure carried by said support hub.

19. The flexible spinal needle assembly of claim 16, wherein said flexible needle further comprises a radially reinforcing material located at a distal end of said flexible needle, said reinforcing material resisting peel-back of said flexible needle from said support needle.

20. The flexible spinal needle assembly of claim 16, having a distal end of said flexible needle being constructed to provide a perceptible feedback signal when said distal end of said flexible needle penetrates said dura mater.

21. The flexible spinal needle assembly of claim 16, characterized in said flexible needle hub further being configured for attachment to medical fluid transfer equipment having structure to form a luer lock type connection.

22. The flexible spinal needle assembly of claim 16, wherein a flexible needle hub is configured for attachment to medical fluid transfer equipment by an attachment structure to form a connection generally perpendicular to a direction of flexible needle insertion.

23. The flexible spinal needle assembly of claim 16, wherein said flexible needle comprises a flexible kink sleeve disposed on a portion thereof, said flexible kink sleeve configured to prevent kinking of said flexible needle when said flexible needle is extended beyond the substantial flexure point during use.

25. A flexible spinal needle comprising:

a support needle having a pencil point, non-cutting piercing tip, said support needle defining an interior lumen and an opening, said opening communicating said interior lumen with the exterior of said support needle;

a flexible needle body comprising an elongated hollow tube and made of a material that has a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body, but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom, said flexible needle body configured to be removeably and slidably mounted on an exterior of said support needle, said flexible needle body defining a leading edge, said leading edge being positioned contiguous to said opening of said support needle; and

a flexible kink sleeve disposed on a portion of said flexible needle body, said flexible kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent beyond a flexible structural resilience thereof during use

wherein said support needle is positionable in two conditions relative to said flexible needle body; in a first condition said flexible needle body is mounted on said exterior of said support needle, said support needle being positioned with said first end of said support needle extending beyond said leading edge of said flexible needle body, and in a second condition said support needle is removed from physical contact with said flexible needle body.

26. A flexible spinal needle comprising: a flexible needle body comprising an elongated hollow tube, said flexible needle body configured to be slidably mounted on an exterior of a support needle; a flexible needle hub configured for attachment to medical fluid transfer equipment by an attachment structure to form a connection generally perpendicular to a longitudinal axis of said flexible needle body.

27. A flexible spinal needle assembly comprising:

a support needle comprising a first end defining a pencil point, non-cutting piercing point, and a hollow bore with an opening proximate said first end allowing access to said bore; and

a flexible needle removably and slidably mounted on an exterior portion of said support needle such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, said flexible needle made of a material having a sufficiently high tensile strength to maintain structural integrity during and after insertion into and retraction from a patient's body, but also possessing sufficient transverse flexibility to deform and accommodate patient motion after insertion to reduce irritation therefrom and having a leading edge positioned contiguous to the opening of the support needle after insertion, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle, said flexible needle defining a lumen therein for transporting a medicinal agent;

wherein said support needle is positionable in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said first end of said support needle extending beyond said leading edge of said flexible needle, said non-cutting piercing point and said opening being positioned beyond said leading edge, the opening being positioned contiguous to the leading edge, and in a second condition said support needle being removed from physical contact with said flexible needle.

28. The flexible spinal needle assembly of claim 27 wherein the flexible needle comprises a medical grade plastic material and a tip extending axially from the flexible needle body of said flexible needle of substantial extent to be further extendable into the dura mater upon extraction of said support needle.

29. The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle.

30. The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is reinforced with a flat ribbon internal spring disposed within a wall of said flexible needle.

31. The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is reinforced with a metal band.

32. The flexible needle catheter assembly of Claim 1 wherein said flexible needle catheter is disposed on an outer surface of said support needle.

34. The flexible needle catheter assembly of Claim 1 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

35. The flexible spinal needle assembly of Claim 16 wherein said leading edge of the flexible needle is arranged relative to said support needle such that said leading edge of the flexible needle is positioned contiguous to the opening of the support needle after an insertion of said leading edge into the patient's body.

36. The flexible needle catheter assembly of Claim 16 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

37. The flexible needle catheter assembly of Claim 25 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

38. The flexible needle catheter assembly of Claim 27 wherein a plane containing said leading edge is positioned perpendicularly to a longitudinal axis of said needle assembly.

IX. EVIDENCE APPENDIX

No evidence has been submitted in this case pursuant to 37 C.F.R. § 1.130, 1.131, or 1.132. All evidence referred to in this Brief is comprised in official correspondence between the Examiner and Appellant that is in the record.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings have been identified with respect to the present appeal.